p = 0.006) and diameter stenosis (26.69 ± 20.38% vs. 32.31 ± 16.66%; p = 0.06) at follow-up were better in the PES arm in the "in-stent/balloon" analysis. Interestingly, these differences were not detected in the "in-segment" analysis, suggesting the possibility of an "edge phenomenon" after PES. Although not powered for clinical events, the current study was large, timely, and nicely executed, and it provides novel insights clearly supporting the value of DEB in patients with SVD. Nevertheless, further studies are warranted to demonstrate that DEB outperform PES, or are equivalent to second-generation drug-eluting stents, before they would be widely adopted in this challenging anatomic scenario (5,6).

***Fernando Alfonso, MD, PhD**
Alberto Cárdenas, MD
Cecilia Cuevas, MD
María J. Pérez-Vizcayno, MD

*Interventional Cardiology, Cardiovascular Institute
Clínico San Carlos University Hospital, IdISSC
Madrid, Plaza de Cristo Rey
Madrid 28040
Spain
E-mail: falf@hotmail.com

http://dx.doi.org/10.1016/j.jacc.2012.11.067

REFERENCES

1. Latib A, Colombo A, Castriota F, et al. A randomized multicenter study comparing a paclitaxel drug-eluting balloon with a paclitaxel-eluting stent in small coronary vessels: the BELLO (Balloon Elution and Late Loss Optimization) study. J Am Coll Cardiol 2012;60:2473–80.
2. Loh JP, Waksman R. Paclitaxel drug-coated balloons: a review of current status and emerging applications in native coronary artery de novo lesions. J Am Coll Cardiol Intv 2012;5:1001–12.
3. Kuntz RE, Safian RD, Levine MJ, Reis GJ, Diver DJ, Baim DS. Novel approach to the analysis of restenosis after the use of three new coronary devices. J Am Coll Cardiol 1992;19:1493–9.
4. Alfonso F, Zueco J, Cequier A, et al. A randomized comparison of repeat stenting with balloon angioplasty in patients with in-stent restenosis. J Am Coll Cardiol 2003;42:796–805.
5. Moreno R, Fernández C, Alfonso F, et al. Coronary stenting versus balloon angioplasty in small vessels: a meta-analysis from 11 randomized studies. J Am Coll Cardiol 2004;43:1964–72.
6. Byrne RA, Kastrati A. Lesions in small coronary vessels disease: should drug-coated balloons replace drug-eluting stents as the treatment of choice? EuroIntervention 2011;7 Suppl K:K47–52.

Reply

We thank Dr. White and colleagues and Dr. Alfonso and colleagues for their interest in the BELLO (Balloon Elution and Late Loss Optimization) study, which is to date the largest randomized trial to compare drug-eluting balloons (DEB) with drug-eluting stents in de novo small-vessel disease (1). We agree that there is an intrinsic methodological weakness in comparing late loss with a device known to produce a large immediate gain (stent) versus a device producing a smaller initial gain (balloon) and therefore a lower late loss. This situation has been demonstrated historically in the seminal studies of stent versus balloon angioplasty (2,3), in which the late loss after balloon angioplasty was about one-half of the late loss with a bare-metal stent (about 0.3 mm vs. 0.6 mm). In our study, we face a similar situation but with a difference in the fourth magnitude. This finding cannot be dismissed by the simple statement that the "lower you gain, the less you lose." The fact that the late loss after DEB was 4 times lower than after drug-eluting stents suggests, as expected, that other mechanisms (the drug on the balloon) are in action to lower the percentage of late loss compared with the small gain. This fact is further supported by the lack of difference in binary restenosis numerically and statistically.

Furthermore, we would like to take the opportunity to highlight the absolute value of late loss after DEB in BELLO (0.08 ± 0.38 mm). This value is considerably lower than the values seen with competitor DEBs in de novo disease: 0.32 ± 0.56 mm overall and 0.18 ± 0.38 mm for DEB only in the PEPCAD I (Paclitaxel-Eluting PTCA-Balloon to Treat Small Vessel) study (4) or the 0.38 ± 0.39 mm (personal communication, January 2013, from Eurocor GmbH) result found in the Valentines Trial II. We want to take the opportunity in this letter to reaffirm that we are not claiming superiority of a balloon procedure compared with a drug-eluting stent procedure regarding final and follow-up lumen dimensions. Instead, our goal is to provide data supporting the possibility of using an alternative procedure (DEB) in situations in which stenting may not be considered ideal.

***Antonio Colombo, MD**
Azeem Latib, MD

*EMO-GVM Centro Cuore Columbus
Via Buonarroti 48
Milan 20145
Italy
E-mail: info@emocolumbus.it

http://dx.doi.org/10.1016/j.jacc.2013.01.013

REFERENCES

1. Latib A, Colombo A, Castriota F, et al. A randomized multicenter study comparing a paclitaxel drug-eluting balloon with a paclitaxel-eluting stent in small coronary vessels: the BELLO (Balloon Elution and Late Loss Optimization) study. J Am Coll Cardiol 2012;60:2473–80.
2. Serruys PW, de Jaegere P, Kiemeneij F, et al. A comparison of balloon-expandable-stent implantation with balloon angioplasty in patients with coronary artery disease. Benestent Study Group. N Engl J Med 1994;331:489–95.
3. Fischman DL, Leon MB, Baim DS, et al. A randomized comparison of coronary-stent placement and balloon angioplasty in the treatment of coronary artery disease. Stent Restenosis Study Investigators. N Engl J Med 1994;331:496–501.
4. Unverdorben M, Kleber FX, Heuer H, et al. Treatment of small coronary arteries with a paclitaxel-coated balloon catheter. Clin Res Cardiol 2010;99:165–74.

Potential Impact of Concomitant Valvular Lesions and Coronary Artery Bypass Surgery on Outcome in Low-Gradient Severe Aortic Stenosis With Preserved Ejection Fraction

We read with interest the study by Clavel et al. (1). The investigators sought to compare outcomes among 3 groups of patients: those with the syndrome of paradoxical low-flow, low-gradient (LF/LG)